

DEC 14 1998

DADE BEHRING INC.  
P.O. Box 6101  
Newark, DE 19714

DADE BEHRING

K984193

**Summary of Safety and Effectiveness Information**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Submitter's Name:** Rebecca S. Ayash  
Dade Behring Inc.  
Building 500, Mailbox 514  
P.O. Box 6101  
Newark, DE 19714-6101  
Phone: (302) 631-6276  
FAX: (302) 631-6299

**Date of Preparation:** 11/20/98

**Device Name:** Dimension® RxL Myoglobin (MYO) Calibrator

**Classification Name:** Calibrator, secondary

**Predicate Device:** Dade Behring Stratus® Myoglobin Calibrator

**Device Description:** MYO Calibrator is a five level liquid bovine serum albumin-based product with target concentrations of 0, 35, 100, 500, and 1060 ng/mL. Level 1 contains no detectable myoglobin. Levels 2 through 5 contain human heart myoglobin. The kit consists of ten vials; two at each level

**Intended Use:** The MYO Calibrator is intended to be used to calibrate the MYO Method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module.

**Comparison to Predicate Device:**

	Dimension® RxL MYO Calibrator	Stratus® Myoglobin Calibrator
Intended Use	Calibrator	Calibrator
Analyte	Human heart myoglobin	Human heart myoglobin
Matrix	Bovine serum albumin	Bovine serum albumin
Form	Liquid	Liquid
Target Concentrations (ng/mL)	0, 35, 100, 500, 1060	0, 35, 100, 300, 500, 1000
Levels	Five	Six



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 14 1998

Ms. Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Dade Behring  
Building 500, Mailbox 514  
P.O. Box 6101  
Newark, Delaware 19714-6101

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Re: K984193  
Trade Name: Dimension® RxL Myoglobin (MYO) Calibrator  
Regulatory Class: II  
Product Code: JIT  
Dated: November 20, 1998  
Received: November 23, 1998

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

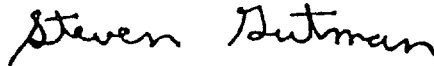
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

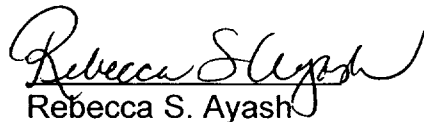
Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications Statement

**Device Name:** Dimension® RxL Myoglobin (MYO) Calibrator

**Indications for Use:** The Dimension® RxL Myoglobin (MYO) Calibrator is intended to be used to calibrate the Myoglobin Method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module.



Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Date: 11/20/98

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K984193  
510(k) Number



Division Sign-Off  
Office of Device Evaluation

✓ prescription use